K133192

JUN 2 3 2014

Appendix 2

510(K) Summary
Nitrile Examination Gloves Powder Free,Orange colour

1.0 Submitter :

Company Name : Riverstone Resources Sdn.Bhd.

Company Address : Lot 55&56,No.13&15 Jalaln Jasmin 2,
Kawasan Perindustrian Bukit Beruntung,
48300 Bukit Beruntung
Selangor,Malaysia.

Contact Person : Mr Suresh Kumar

Telephone No : 603-60283033

Email : qa1 @riverstone.com.my

2.0 Preparation Date : 7th May 2014

3.0 Name of the Device

Trade Name / Proprietary Name : RS Orange Nitrile Medical Examination Gloves (Powder Free)

Device Name : Nitrile Patient Examination gloves

Device Classification Name : Patient Examination gloves (21 CFR 880.6250)

Device Class : Class I

Product Code : Nitrile-LZA

4.0 Identification of The Legally Marketed Device :

Class I patient Examination gloves,Powder Free,LZA which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250.It is equivalent to K 100603, RS Safe Blue Nitrile Medical Examination Gloves Powder Free (Non-Sterile) and K112928, RS White Nitrile Examination glove Powder Free (Non Sterile) except for colour.

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5.0 Description of Device

Orange Nitrile Medical Examination gloves powder free, non sterile, as described in this 510(k) Notification is substantially equivalent to the current class I patient examination gloves with product Code LZA (21CFR 880.6250). It meets all the specifications in ASTM D6319-10, Standard specification for Nitrile Examination Gloves. They are made nitrile from nitrile latex compound, orange colour, powder free and non sterile.

6.0 Intended use of the Device

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. It is for over-the-counter use.

7.0 Summary of the Technological Characteristics of the Device compared to the Predicate Device for substantial equivalent discussion

There is no different technology characteristics compared to the predicate device expect colour. Gloves are made from nitrile latex compound, Orange colour, powder free and non sterile. It is equivalent to K 100603, RS Safe Blue Nitrile Medical Examination Gloves Powder Free (Non-Sterile) and K112928 ,RS White Nitrile Medical Examination Glove Powder Free (Non Sterile) except for colour.

Appendix 2

Characteristics	RS Orange Nitrile Medical Examination Gloves (Powder Free) K133193	RS Safe Blue Nitrile Medical Examination Gloves Powder Free (Non-Sterile) K 100603	RS White Nitrile Medical Examination Gloves Powder Free (Non-Sterile) K 112928
Product Code	LZA	LZA	LZA
Intended use	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.
Material use	Nitrile latex compound	Nitrile latex compound	Nitrile latex compound
Colour	Orange	Blue	White
Sterility	Non sterile	Non sterile	Non sterile
Dimensions	Meets ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10
Physical properties	Meets ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10
Freedom from pinholes	Meets ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10
Powder –Free	Meets ASTM D6319-10	Meets ASTM D6319-10	Meets ASTM D6319-10
Biocompatability test- Primary Skin Irritation Test	Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, the test article was a non-irritant.
Dermal Sensitization Assay	Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.

Appendix 2

RS Orange Nitrile Medical Examination Gloves Powder Free posting the following technological characteristics

compared to ASTM or Equivalent standards:

Characteristics	**Standards**	**Device Performance RS ORANGE Orange Nitrile Medical Examination Gloves Powder Free (Non-Sterile)**
Dimension	ASTM D 6319-10	Meets
Physical Properties	ASTM D 6319-10	Meets
Freedom from pinhole	ASTM D 6319-10	Meets
Powder -Free	ASTM D 6319-10	Meets
Biocompatability	Primary Skin Irritation Test Consumer Product Safety Commission, Title 16, Chapter II, Part 1500	Under the conditions of this study, the test article was a non-irritant
	Dermal Sensitization Assay- ISO 10993-10:2010(E)	Under the conditions of this study, the test article was a non-sensitizer.

8.0
Conclusion

It can be concluded that Orange Nitrile Medical Examination Gloves (Powder Free) will perform according to the glove performance standards ASTM D 6319-10, biocompatibility requirement and FDA requirements and the labeling claims for the product. Performance testing data demonstrates , RS Orange Nitrile Medical Examination Glove (Powder Free) is substantially equivalent to the predicate devices (K100603 and K112928)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 23, 2014

Riverstone Resources Sdn Bhd
Mr. Suresh Kumar
QA Manager
Lot 55&56, No.13&15 Jalan Jasmin 2,
Kawasan Perindustrian Bukit Beruntung
Selangor MALAYSIA 48300

Re: K133193
Trade/Device Name: RS Orange Nitrile Medical Examination Gloves (Powder Free)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA
Dated: May 23, 2014
Received: May 27, 2014

Dear Mr. Kumar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133193

Device Name
RS Orange Nitrile Medical Examination Gloves (Powder Free)

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
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